

REMARKS

Claims 1-20 are presently pending in the present application, with claims 5, 10, 11, and 17-20 having been withdrawn in connection with a prior restriction requirement. Thus claims 1-4, 6-9, and 12-16 have been examined.

All prior rejections in the present application have been removed. However, the Office Action indicated that the Applicant's prior amendments necessitated "new grounds of rejection" and made these new rejections final rejections.

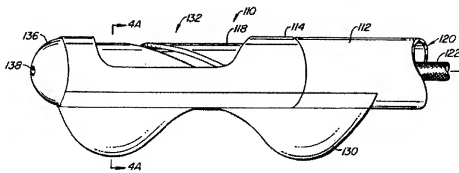
§102(b) Rejection - U.S. Patent No. 5,242,460

The Office Action rejected claims 1, 3, 6-9, and 12-16 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,242,460 to Klein et al ("Klein").

Claim 1

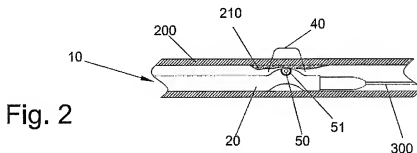
Klein does not teach, for example, a catheter having "a controllably arcuate segment formed in the shaft and including at least one opening ..." Additionally, Klein teaches a catheter that maintains the material to be removed within the cutting head, rather than moving it down the catheter shaft for aspiration. Thus, for several reasons, Klein does not anticipate claim 1.

Specifically, Klein's FIG. 1 includes all of the elements cited in the Office Action as anticipating the catheter of claim 1, shown in part below.



The Office Action states that Klein's *cylindrical housing 114* anticipates the "controllably arcuate segment ..." of claim 1. This simply is not the case. Klein never states or shows that the shape of its *cylindrical housing 114* can be controlled, nor that it can be controlled to be arcuate. Klein indicates that balloon 130 can be inflated and that the cutting head 118 can be rotated, but never states or shows that its *cylindrical housing 114* is controllably arcuate.

Applicant notes that Klein mentions that its catheter body 112 can be a "flexible tube." Generally, catheters tend to be flexible to facilitate translation into and out of a body. However, a controllably arcuate segment goes far beyond a mere flexible tube, and serves a purpose far different than facilitating translation of the catheter into and out of the body. Klein never says that its catheter body includes a controllably arcuate segment. For clarification, an embodiment of a controllably arcuate segment, as in claim 1, is shown as *controllably arcuate segment 40* in FIGS. 1A, 1B, 2 and 3-3B, i.e., a segment of the catheter shaft that can be deliberately made to be in the shape of an arc under control of a user. A comparison of FIG. 2 of the present application (reproduced below), as an example, and FIG. 1 (above) of Klein are good illustrations of the differences.



Also, the Klein's *rotating* cutting head 118 is not a *sliding* member as required in claim.

Additionally, Klein teaches away from moving the material to be removed down the shaft and away from the opening, as is facilitated by the structure of the sliding member of claim 1. Rather, Klein teaches that the material (i.e., "severed atheromas") is "retained within the cutting head" to avoid aspiration. (See Klein, col. 4 lines 28-33, and col. 7, lines 55-59)

Therefore, for several reasons, claim 1 is not anticipated under 35 U.S.C. §102(b) by Klein. Accordingly, Applicant requests reconsideration and withdrawal of the rejection to claim 1.

Claims 3, 6-9, and 12-16

With respect to claim 3, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 3, which further comprises “an aspiration chamber near the proximal end, said aspiration chamber in fluid communication with the material collection chamber.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 3.

With respect to claim 6, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 6, “wherein the material collection chamber is proximal to the controllably arcuate segment.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 6.

With respect to claim 7, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 7, which further comprises “a material extraction lumen between the distal end of the catheter shaft and an aspiration port located on the proximal portion of the device.” In fact, the Office Action offers no showing of an aspiration port in Klein, which is required by claim 7. Since Klein teaches away from aspiration of the material, e.g., in col. 4 lines 28-34:

Severed atheromas will be largely retained within the cutting head until they can be withdrawn from the patient, thereby affording means for withdrawing the material that does not require aspiration and the design complexities that accompany use of aspiration means.

Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 7.

With respect to claim 8, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 8, “wherein the controllably arcuate segment has a normally bowed bias.” In addition to the comments provided above with respect to claim 1, Klein does not discuss the arcuate segment having a *normally bowed bias*, as in this

claim. In fact, Klein's cylindrical shaft 114 is never shown or described as being bowed. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 8.

With respect to claim 9, as with claim 8 from which claim 9 depends, Klein does not anticipate the catheter of claim 9, "wherein positioning of the sliding member within the controllably arcuate segment causes said arcuate segment to be relatively straight." Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 9.

With respect to claim 12, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 12, "wherein the sliding member has a cutting edge on the end facing the opening in the controllably arcuate segment." In fact, in Klein cutting head 118 is taught as being rotational – not configured for sliding. (see, e.g., Klein col. 5, lines 13-17; col. 7, lines 16-20) Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 12.

With respect to claim 13, as with claim 1 from which it depends, Klein does not anticipate the catheter of claim 13, "wherein the sliding member is attached to a flexible shaft, said shaft traversing the length of the catheter and said sliding member advanced and retracted by advancing and retracting said shaft from controls located on the proximal end of said catheter." In fact, the Office Action never offered any citation within Klein to show "said shaft traversing the length of the catheter and said sliding member advanced and retracted by advancing and retracting said shaft from controls located on the proximal end of said catheter" of claim 13. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 13.

With respect to claim 14, as with claim 1, Klein does not anticipate the catheter of claim 14, which further comprises "a rotational orientation element." Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 14.

Claims 15 and 16

Applicant requests removal of the rejections under 35 U.S.C. 102(b) to claims 15 and 16 as being anticipated by Klein. The Office Action offered no text that states how

Klein anticipates each and every element of independent claim 15 and its dependent claim 16.

Claim 15 has elements similar to those discussed above with respect to claim 1, so is similarly not anticipated by Klein. For example, as discussed with respect to claim 1, Klein does not anticipate a catheter having a *controllably arcuate segment* of a catheter shaft.

Claim 15 also includes elements not in claim 1 and never addressed in the Office Action, nor are they present in Klein. Specifically, nowhere does the Office Action address how Klein anticipates the “aspiration port configured to receive a vacuum input” or “an aspiration lumen configured to form a vacuum path” of claim 15. As a result, it has not been shown that, with respect to claims 15 and 16, “the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States” as required under 35 U.S.C. 102(b).

In fact, as noted above with respect to claims 1 and 7, Klein teaches away from aspiration of the removed material – explicitly opting to retain within the cutting head until removal of the catheter from the patient’s body.

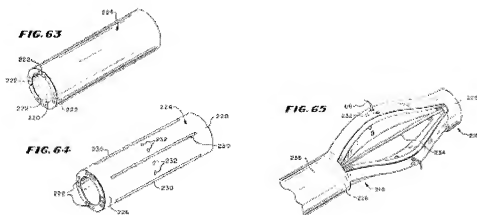
Therefore, for several reasons, Applicant respectfully requests withdrawal of the rejection to claim 15.

With respect to claim 16, which depends from claim 15, Klein does not anticipate the catheter of claim 16, which further comprises “a sliding member movably disposed within the shaft and configured to selectively traverse the at least one opening to moves the material received through the at least one opening away from said at least one openings and toward the aspiration chamber.” As discussed above with respect to claim 1, the *rotating* cutting head 118 of Klein is not a *sliding* member. Also, as noted above the Office Action did not present any ground for rejecting this claim. Accordingly, for several reasons. Applicant requests reconsideration and withdrawal of the rejection of claim 16.

§102(b) Rejection - U.S. Patent No. 6,326,798

The Office Action rejected claims 1-4, 6-9, and 12-16 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,326,798 to Edwards et al. ("Edwards").

The Office Action cited FIG. 65 of Edwards as anticipating claim 1. FIG. 65 is the 3rd in a series of three figures (63-65) that disclose Edwards' the basket structure cited as teaching the controllably arcuate segment of claim 1, and formation thereof. These three figures are reproduced below for convenience.



Specifically, the Office Action asserts that the controllably arcuate segment of claim 1 is taught by the extruded basket structure 218 and the sliding member is taught by wire 234 of Edwards. Fundamentally, the device of Edwards is structured to deploy a carrier of an electrode that can be advanced to penetrate tissue. (See *Edwards*, Abstract), as opposed to the catheter of claim 1 which is structured to remove a material.

Additionally, the extruded basket structure 218 is not a *controllably arcuate segment* as in claim 1, the relevant claim 1 element is reproduced below:

a controllably arcuate segment formed in the shaft and including at least one opening configured to receive into the shaft a material exteriorly proximate to the at least one opening

The shape of the extruded basket structure 218 of Edwards is not "arcuate" – i.e., it is not in the shape of an arc. For example, the OneLook.com online dictionary defines *arcuate* to mean: "forming or resembling an arch." The use of the term *arcuate* for a segment of the shaft in the specification and claims is consistent with such a definition.

(see, e.g., FIG. 2 of the present application provided above) Edwards' extruded basket structure 218 does not satisfy this definition.

Meanwhile, the OneLook.com online dictionary defines a *bulb* as: "a rounded part of a cylindrical instrument (usually at one end)." The extruded basket structure 218 of Edwards is bulb-shaped (as shown in FIG. 65), not arcuate. Individual members of the extruded basket structure 218 may individually have an arc shape, but the overall shape of the extruded basket structure 218 is of a bulb – not an arc. Thus, in Edwards, the segment of the shaft having the extruded basket structure 218 is bulb-shaped – not arcuate as required by claim 1.

Additionally, the wire 234 of Edwards is not the sliding member of claim 1 as suggested in the Office Action, the relevant element is reproduced below:

a sliding member movably disposed within the shaft and configured to selectively traverse the at least one opening to move the material received through the at least one opening into the material collection chamber and away from said at least one opening

For example, the wire 234 in Edwards is merely used to pull the distal end toward the catheter tube 236 (described in Edwards, col. 26, line 47 through col. 27, line 24), so that the extruded basket structure 218 can be formed from the extruded tube in Edwards' FIGS. 63 and 64. For example, compare the simple wire 234 of Edwards with the sliding member 100 of FIG. 3 of the present application, as an example. The wire 234 of Edwards cannot move material, it would simply move through material. Clearly, the simple wire 234 of Edwards does not anticipate a "sliding member ... configured to selectively ... move the material received through the at least one opening into the material collection chamber and away from said at least one opening." Since Edwards teaches a delivery catheter and not a removal catheter, there would be no need for the sliding member of claim 1 in Edwards; and Edwards does not disclose one.

Therefore, for several reasons, claim 1 is not anticipated under 35 U.S.C. §102(b) by Edwards. Accordingly, Applicant requests reconsideration and withdrawal of the rejection to claim 1.

Claims 2-4, 6-9, and 12-16

With respect to claim 2, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 2, which further comprises “suction means near the proximal end, said suction means in fluid communication with the opening in the controllably arcuate segment.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 2.

With respect to claim 3, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 3, which further comprises “an aspiration chamber near the proximal end, said aspiration chamber in fluid communication with the material collection chamber.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 3.

With respect to claim 4, as with claim 3 from which it depends, Edwards does not anticipate the catheter of claim 4, which further comprises “further comprising a one-way valve located between the aspiration chamber and the material collection chamber, said valve oriented to allow material to flow from the material collection chamber to the aspiration port.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 4.

With respect to claim 6, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 6, “wherein the material collection chamber is proximal to the controllably arcuate segment.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 6.

With respect to claim 7, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 7, which further comprises “a material extraction lumen between the distal end of the catheter shaft and an aspiration port located on the proximal portion of the device.” Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 7.

With respect to claim 8, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 8, “wherein the controllably arcuate segment has a normally bowed bias.” In addition to the comments provided above with respect to claim 1, Edwards does not discuss the arcuate segment having a *normally bowed bias*, as in this

claim. In Edwards, the extruded basket structure 218 does not have a normally bowed bias. The opposite is in fact true in Edwards, as demonstrated in Edwards' FIGS. 63 and 64. The extruded portion is normally cylindrical, but pulled into a bulb shape when the wire 234 is pulled toward the catheter tube 236. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 8.

With respect to claim 9, as with claim 8 from which claim 9 depends, Edwards does not anticipate the catheter of claim 9, "wherein positioning of the sliding member within the controllably arcuate segment causes said arcuate segment to be relatively straight." Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 9.

With respect to claim 12, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 12, "wherein the sliding member has a cutting edge on the end facing the opening in the controllably arcuate segment." Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 12.

With respect to claim 13, as with claim 1 from which it depends, Edwards does not anticipate the catheter of claim 13, "wherein the sliding member is attached to a flexible shaft, said shaft traversing the length of the catheter and said sliding member advanced and retracted by advancing and retracting said shaft from controls located on the proximal end of said catheter." In fact, the Office Action never offered any citation within Edwards to show "said shaft traversing the length of the catheter and said sliding member advanced and retracted by advancing and retracting said shaft from controls located on the proximal end of said catheter" of claim 13. Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 13.

With respect to claim 14, as with claim 1, Edwards does not anticipate the catheter of claim 14, which further comprises "a rotational orientation element." Accordingly, Applicant requests reconsideration and withdrawal of the rejection of claim 14.

Claims 15 and 16

Applicant requests removal of the rejections under 35 U.S.C. 102(b) to claims 15 and 16 as being anticipated by Edwards. The Office Action offered no text that states how Edwards anticipates each and every element of independent claim 15 and its dependent claim 16.

Claim 15 has elements similar to those discussed above with respect to claim 1, so is similarly not anticipated by Edwards. For example, as discussed with respect to claim 1, Edwards does not anticipate a catheter having a *controllably arcuate segment* of a catheter shaft.

Claim 15 also includes elements not in claim 1 and never addressed in the Office Action, nor are they present in Edwards. Specifically, nowhere does the Office Action address how Edwards anticipates the “aspiration port configured to receive a vacuum input” or “an aspiration lumen configured to form a vacuum path” of claim 15. As a result, it has not been shown that, with respect to claims 15 and 16, “the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States” as required under 35 U.S.C. 102(b).

Additionally, as discussed with respect to claim 1, Edwards does not anticipate a catheter having a *controllably arcuate segment* of a catheter shaft.

Therefore, for several reasons, Applicant respectfully requests withdrawal of the rejection to claim 15.

With respect to claim 16, which depends from claim 15, Edwards does not anticipate the catheter of claim 16, which further comprises “a sliding member movably disposed within the shaft and configured to selectively traverse the at least one opening to moves the material received through the at least one opening away from said at least one openings and toward the aspiration chamber.” As discussed above with respect to claim 1, the wire 234 of Edwards is not a *sliding* member. Also, as noted above the Office Action did not present any ground for rejecting this claim. Accordingly, for several reasons. Applicant requests reconsideration and withdrawal of the rejection of claim 16.

Closing Remarks

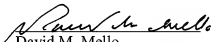
It is submitted that all of examined claims 1-4, 6-9, and 12-16 are in condition for allowance, and such allowance is respectfully requested. Removal of the final rejection and allowance of the above claims is requested.

If prosecution of the application can be expedited by a telephone conference, the Examiner is invited to call the undersigned at the number given below.

Authorization is hereby given to charge Deposit Account No. 501798 for all otherwise unpaid fees due with this response.

Respectfully submitted,

Date: Sept. 13, 2006
Mills & Onello, LLP
Eleven Beacon Street, Suite 605
Boston, MA 02108
Telephone: (617) 994-4900, Ext. 4959
Facsimile: (617) 742-7774


David M. Mello
Registration Number 43,799
Attorney for Applicant